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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,471	07/27/2001	Leland F. Wilson	9050-0053	3484

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EXAMINER
HUI, SAN MING R

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 05/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/919,471	WILSON ET AL.	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) *13-15,19,46-49 and 51-54* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,16-18,20-45 and 50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's election without traverse of the invention of Group I, claims 1-45 and 50 in Paper No. 3, received February 19, 2002 is acknowledged.

In addition, Applicant's election without traverse of the specie of dihydrotestosterone propionate in Paper No. 3, received February 19, 2002 is acknowledged.

Claims 46-49 and 51-54 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 13-15 and 19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 3.

The claims have been examined herein to the extent they read on the elected invention and species.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant fails to set forth the criteria in the specification that defines "lipoidal carrier effective to enhance the oral bioavailability of the androgenic agent". Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. In the instant case, no "lipoidal carrier" examples is set forth. Applicants fail to provide information sufficient to practice the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12, 16-18, 20-45, and 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression "regular dosing within the context of a chronic dosage regimen" in claims 1 and 50 renders the claims indefinite as to the dosing frequency of the active agent encompassed by the claims herein. The examiner would favorably consider the deletion of the phrase because "as-needed basis" means that the agent is not administered regularly.

The term "lipoidal carrier" in claim 20 renders the claim indefinite because it is unclear what carriers are encompassed by the claims which would enhance the bioavailability of the androgenic agents herein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-12, 16-18, 20-45, and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (WO 99/66909) and Place et al. (US Patent 5,877,216).

Adams teaches a method of treating female sexual dysfunction employing a dopaminergic agonist, apomorphine and concomitantly with an androgenic agent such as dihydrotestosteroneand its ester (See claims 1-3, 11-12). Adams also teaches that the androgenic agent may be administered orally (See page 21, line 13-25). Adams also teaches that dihydrotestosterone may be administered prior to or concomitantly with apomorphine (See claims 16-17). Adam also teaches that 480μg/kg dose of one of the androgenic agent, testosterone, 36 hours prior to the administration of apomorphine are effective to alleviate sexual dysfunction or normalize sexual dysfunction in post-menopausal and pre-menopausal women (See page 32, line 10-23).

Adams does not expressly teach the androgenic agent is dihydrotestosterone propionate. Adams does not expressly teach the addition agent to be a prostaglandins or prostaglandin derivative such as carboprost tromethamine. Adams does not expressly teach the addition agent to be administered topically. Adams does not expressly teach the dosing regimen and dosage of the androgenic agent and the secondary active herein. Adams does not expressly teach the employment of a lipoidal

carrier to enhance the bioavailability of the androgenic agent. Adams also teaches that the active agents can be formulated into unit dosage form (See page 22, line 5-11).

Place et al. teaches PGE_0 or carboprost tromethamine topical administration is effective in a method of treating female sexual dysfunction (See claims 5 and 9). Place et al. also teaches steroids such as dihydrotestosterone may be employed with the prostaglandins in the method of treating female sexual dysfunction (See claim 10; also col. 8, line 32-47). Place et al. also teaches an additional agent such as detergent may be incorporated into the female sexual dysfunction treating method in increase the solubility and bioavailability of active agents (See particularly claim 13). Place et al. also teaches that the pharmaceutical composition therein can be formulated into liposomal formulation (See particularly claim 20). Place et al. also teaches that the dosage of prostaglandin for the treatment of female sexual dysfunction would be at least the dosage of dyspareunia treatment which is 50 to 500μg/kg (around 3 to 30mg for an average 60kg female) (see col. 13, line 41-51).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ dihydrotestosterone propionate with a second active agent such as PGE_0, carboprost tromethamine, or apomorphine, in the dosage range and regimen herein, in the method of treating female sexual dysfunction. It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a lipoidal carrier to enhance the bioavailability of the androgenic agent.

One of ordinary skill in the art would have been motivated to employ dihydrotestosterone propionate with a second active agent such as PGE_0, carboprost

tromethamine, or apomorphine, in the dosage range and regimen herein, in the method of treating female sexual dysfunction because all of the dihydrotestosterone esters are known to be useful in treating female sexual dysfunction. Employing dihydrotestosterone propionate would have been reasonably expected to be similarly useful for treating female sexual dysfunction. Employing a second active agent such as PGE_0, carboprost tromethamine, or apomorphine into the method of treating female sexual dysfunction would have been reasonably expected to be effective based on the teachings of Adams and Place et al. Combining two or more agents which are known to be useful to treat female sexual dysfunction individually into a single composition and method useful for the very same purpose is prima facie obvious. See *In re Kerkhoven* 205 USPQ 1069. Furthermore, the optimization of result effect parameters (dosage range, dosing regimens) is obvious as being within the skill of the artisan.

One of ordinary skill in the art would have been motivated to employ a lipoidal carrier to enhance the bioavailability of the androgenic agent because based on Place et al. additive such as detergent can enhance the bioavailability of the active compounds. Therefore, employing a detergent into the liposomal formulation useful for treating female sexual dysfunction would have been reasonably expected to be useful for enhancing the bioavailability of the actives herein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-

1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
May 5, 2002